

Attorney Docket No.: J3677(C)  
Serial No.: 10/521,842  
Filed: July 14, 2005  
Confirmation No.: 1292

### REMARKS

Claim 1 has been amended to incorporate the requirements of 4 which specifies that the weight ratio of the amount of tulsi oil to the amount of metal pyrrhione lies within the range of from 1:2 to 1:50. Claim 4 has been cancelled without prejudice. Entry of the subject amendments is respectfully requested.

Pursuant to the Office Action of June 18, 2009, pending claims 1-12 were rejected:

- (a) under 35 U.S.C. 102(b) as anticipated by Vermeer (US 5641480),
- (b) under 35U.S.C. 103(a) over Vermeer in view of Solanki (US2003/0152585), and
- (c) under 35 U.S.C. 103(a) over Vermeer in view of Doshi et al. (US 2003/0228382) and further in view of Solanki. These rejections are respectfully traversed.

Before addressing these rejections, it is noted that *Ocimum* is a large genus of mints belonging to the family known as Labiatae. Herbs known as basilis are included in this class. There are many different species of basil including *Ocimum Sanctus* (commonly known as holy basil) and *Ocimum Basilicum*, (commonly known as sweet basil). As noted in Kirk-Othmer Encyclopedia of Chemical Technology, Fourth Edition, Vol. 11, page 53 (copy attached):

Basil is one of the oldest known herbs, and it is reported that there are perhaps 50-60 poorly defined *Ocimum* species which can only be identified according to their chemical components.

Basilis oils can vary with respect to their compositional make-up which, in turn, can affect the physical and/or chemical properties thereof. Tulsi oil is the oil extract of a particular basil, i.e., *Ocimum Sanctum*.

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Pursuant to the subject invention it was found that tulsi oil acts synergistically with metal pyrithione to provide an antimicrobial effect against *M. furfur*, the yeast commonly associated with and believed by some to be the main cause of dandruff. The subject application discloses that the ratio of tulsi oil to synthetic antimicrobial agent for the most effective antidandruff effect is from 1:2 to 1:50, which ratio is reflected in amended claim 1.

Vermeer is directed to hair care compositions comprising heteroatom - containing alkyl aldonamide compounds, which compounds are disclosed to provide compositions with improved viscosity and clarity. The hair care compositions into which the heteroatom-containing alkyl aldonamide compounds can be incorporated into are many and diverse. Such compositions are said to include rinses, conditioners, shampoos, conditioning shampoos, antidandruff shampoos, anti-lice shampoos, coloring shampoos, curl maintenance shampoos, baby shampoos, herbal shampoos, hair loss prevention shampoos, hair growth promoting/stimulating shampoos, hairwave neutralizing shampoos, hair setting products, hair sprays, hair styling products, permanent wave products, hair straightening/relaxing products, mousses, hair lotions, hair tonics, hair pomade products, brilliantines and the like. See, for example, column 34, lines 25 to 36. The additives listed as potential optional ingredients are also many and diverse. For example, the list of emulsifiers/emollients, conditioning emollient oils, and conditioning extracts spans column 34 line 4 to column 35, line 6 and includes over 150 different materials. Basil oil is included among the extensive list of conditioning emollient oils, referenced for their ability, as oils, to condition the hair and scalp. Metal pyrithiones are included among Vermeer's list of antidandruff agents, which list also includes menthol, sulfur, salicylic acid, piroctone olamine, hexachlorophene, resorcinol, coal tar, coal tar extract, coal tar solution, and cetyldimethylbenzylammonium bromide. Other possible optional ingredients, include surfactants, hair styling agents, viscosity control agents.

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dispersants, humectants, solubilizing/clarifying agents, stabilizers, sun-screens/UV absorbers, opacifiers/pearlescent agents, vitamins, amino acids, proteins, curl enhancing agents, hair coloring agents, chelating/sequestering agents, hydrotropes, anti-lice agents, bactericides/fungicides, antioxidants, brightening agents, pH control agents, buffering agents, colorants and perfumes/fragrances, with the list of such agents spanning several pages. Given the extensive list of optional components, literally tens of thousands of ingredient combinations, if not more, are possible. There is nothing in the citation that discloses or suggests combining tulsi oil (the oil extract of *Ocimum Sanctum*) and metal pyrithione in the claimed ratio. Indeed, tulsi oil is nowhere mentioned in Vermeer, its disclosure being limited to that of "basil oil" generically. Further there is nothing in the citation that in any way discloses or suggests to one skilled in the art to combine a specific basil oil, i.e., tulsi oil and metal pyrithione in the claimed ratio as a means of synergistically enhancing the antidandruff efficacy of metal pyrithione.

Solanki is directed to the use of a mixture of seven different herbs (one of which is *ocimum sanctum*) which is said to be effective for the treatment of cancer, in particular, haematological malignancies. There is nothing in the citation in any way concerned with the treatment of dandruff or suggestive of the instant combination of tulsi oil and metal pyrithione.

Doshi et al. discloses herbal cough formulations that is a blend of several different extracts including extracts of *ocimum sanctum*. In the context of the disclosed cough formulations *ocimum sanctum* is said to have an anti-inflammatory antibacterial and stimulating expectorant action. There is nothing in the citation in any way concerned with the treatment of dandruff or suggestive of the instant combination of tulsi oil and metal pyrithione.

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One skilled in the art reading Solanki, Doshi and Vermeer alone or in combination would have no reason to believe that tulsi oil could be used to potentiate the antidandruff efficacy of zinc metal salts.

Accordingly, it is respectfully submitted that the Office Action fails to establish a case of prima facie obviousness and, moreover, that even if such a case of obviousness were established, that it is rebutted by the showing of a synergistic improvement in efficacy against M. furfur provided by the subject combination of tulsi oil and metal pyrithione. See for example, the data provided in Example 2 of the subject application. It is further noted that while a synergistic effect was noted for the combination of zinc pyrithione and tulsi oil, the combination of tulsi oil and climbazole (another common antidandruff active) was antagonistic, as was the combination of tulsi oil and octopirox (yet another common antidandruff ingredient). Compare Example 2 with Examples 1 and 3. It is respectfully submitted that the benefit afforded by the instant metal pyrithione/tulsi oil combination is unexpected and unpredictable.

In light of the above amendments and remarks, it is respectfully requested that the application be allowed to issue.

If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney kindly requests the Examiner to telephone at the number provided.

Respectfully submitted,  
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**KIRK-OTHMER**

# **ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY**

**FOURTH EDITION**

**VOLUME 11**

**FLAVOR CHARACTERIZATION  
TO  
FUEL CELLS**



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pepper. Allspice is the only significant commercial spice exclusive to the Western Hemisphere. *Pimenta* berries resemble black pepper corns; they are round and up to 0.65 cm in diameter. The berries are hand-picked while green, then slightly fermented and sun-dried, turning them reddish brown. The aroma of *pimenta* berries resembles that of cloves, cinnamon, black pepper, and nutmeg, hence the name allspice or *quatre épices*. Allspice is used to flavor vegetables, fruits, pickles, and spicy table sauces.

**Anise Seed.** Anise seed is the dried, ripe fruit of *Pimpinella anisum* L. (*Umbelliferae*), a member of the parsley family indigenous to Asia Minor, Greece, and Egypt. The bulk of supply comes from Turkey, China, Spain, and Egypt, but it can be cultivated in most temperate climates. Anise seed resembles caraway seed in appearance, but has a sweet, licorice flavor popular in Mediterranean and Latin countries, particularly in beverages, anisette, confectionery, salad dressings, and sausage flavors.

The star anise (*Illicium verum* Hook. f.) is from a small evergreen tree, native to southwest China. When ripe, the hard brown fruits of this tree open up into an eight-pointed star, hence the name. The flavor and aroma of this spice is similar to that of *P. anisum*; the essential oils are of similar composition. The uses are similar but more localized.

**Basil (Sweet Basil).** Basil consists of the brown, dried leaves and tender stems of *Ocimum basilicum* L. (*Labiatae*), an annual native to India, Africa, and Asia, and cultivated in Egypt, southern France, Morocco, the Mediterranean countries, and the United States. Basil is one of the oldest known herbs, and it is reported that there are perhaps 50-60 poorly defined *Ocimum* species which can only be identified according to their chemical components. The flavor of the *basilicum* type is warm, sweet, somewhat pungent, and peculiar, i.e., methyl chavicol and linalool. It is used with meats, fish, certain cheeses, and tomato-based salads. The fresh leaves are ground and known as pesto with pastas. It is the main component of the liqueur Chartreuse.

**Bay (Laurel) Leaves.** These are the dried leaves of *Laurus nobilis* L. (*Lauraceae*), also called sweet bay or laurel tree, an evergreen with shiny green leaves up to 7.6 cm in length. It is not to be confused with the bay rum tree (*Pimenta racemosa* Mill. (*Myrtaceae*)) from Puerto Rico and neighboring islands, or California bay laurel (*Umbellularia californica* Nutt. (*Lauraceae*)). *L. nobilis* has been cultivated since antiquity in Mediterranean countries and is now grown extensively in Turkey, the former Yugoslavia, France, and Central America. The odor of the leaves is delicate but distinctly aromatic; the flavor is slightly bitter and burning. It is used extensively for meats, sauces, meat dishes, bouillabaisse, stews, and for pickling spice.

**Capsicum.** Several important condiments are derived from the dozens of species and varieties of the genus *Capsicum* (*Solanaceae*), the nightshade family, particularly from *C. annuum* L., i.e., paprika, red pepper, and cayenne pepper. These plants are indigenous to Mexico, Central America, the West Indies, and much of South America. Capsicums are sensitive to climatic and soil conditions. Many horticultural varieties have been developed, differing in size, shape, taste, pungency, and color. Capsicum can be divided into two general groups, the sweet and the pungent.